



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/028,871	02/19/98	GRANS	98-40012-05

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EXAMINER
SPIVACK, P

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 07/16/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/028,871

Applicant(s)
Gans

Examiner
Phyllis G. Spivack

Group Art Unit
1614



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-9 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-9 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1614

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuisz, U.S. Patent No. 5,518,730, particularly in view of Williams et al., The Lancet.

Fuisz teaches the administration of a controlled release oral dosage form comprising tetracycline. See column 1, lines 25-26, where the minimization or elimination of side effects is disclosed. Fuisz does not focus on the specific vestibular side effects associated with tetracycline administration. Williams teaches the occurrence of vestibular side effects, as vertigo or dizziness, following tetracycline, specifically minocycline, administration. Therefore, in view of the combined teachings of Fuisz and Williams, one having ordinary skill in the art would have been motivated to administer a slowly dissolving, or controlled release formulation of tetracycline in the treatment of acne. Such would have been obvious in the absence of evidence to the contrary because Fuisz teaches a decreased incidence of side effects when a drug entity is released by controlled means. Thus it would have been reasonable to expect the occurrence of vestibular side effects to be reduced following tetracycline therapy by controlled release.

No claim is allowed.

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Applicant is encouraged to submit an information disclosure statement, if one is contemplated, as soon as possible.

Any inquiry concerning this communication should be directed to Phyllis Spivack at telephone number (703) 308-4703.

July 14, 1998

Phyllis Spivack

**PHYLLIS SPIVACK
PRIMARY EXAMINER**